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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,433	08/10/2000	Mark C. Noe	PC10491A	6255

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EXAMINER	
MCKENZIE, THOMAS C	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,433	NOE ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to arguments filed on 11/3/03/. Applicant has not amended any claims. There are five claims pending and five under consideration. Claims 16-20 are use claims. This is the fifth action on the merits. The application concerns some uses of aggrecanase inhibitors having both a carboxylic acid hydroxamide functional group and a phenol benzyl ether.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What chemical structure is implied by the wavy line in the upper right hand corner of the formula of claim 16? Dangling valences are not permitted, *Ex parte Diamond* 123 USPQ 167. An essential portion of the molecule whose use is claimed is not defined, *Ex parte Pedlow* 90 USPQ 395.

Applicants argue that the wavy line is an art recognized symbol in organic chemistry and indicates that the benzene ring of the partial structure in claim 16 is attached to "the rest of the molecule". Applicants appear to agree that the essential "rest of the molecule" has been omitted from the claim. Other than the fact, that

the unknown portion of the molecule contains a hydroxyamide functional group what is the formula of the "rest of the molecule"?

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as reasonably to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. What are the chemical structures of the aggrecanase inhibitors whose use Applicants claim? Claim 16 does not contain a complete generic formula. Beyond molecular weight, the presence of a single functional group, a partial structure, and a desired pharmacological activity, Applicants do not demonstrate that they understand the structures of these molecules. According to the MPEP § "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, **structures** [emphasis added], figures, diagrams, and **formulas** [emphasis added], that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of

ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or **structural chemical formulas** [emphasis added], that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.,* 525 U.S. 55, 68, 119 S. Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed. '" *Enzo Biochem*, 296 F.3d at 1324, 63 USPQ2d at 1613." Applicants limited structural information coupled with a single biological property is not sufficient to distinguish the compounds whose use they claim.

Applicants assert that the rejection is "unavailing" and assert that the claim is described. This is not persuasive because assertion is not evidence. Applicants fail to point to any text or reference work that would make the required correlation between biological function and chemical structure, or by a combination of such

identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen)." "It is only a definition of a useful result rather than a definition of what achieves that result." "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")".

This case was filed before Applicants had a clear idea of the structures of their desired compounds, how to make their compounds, and use the compositions made from them. The specification provides broad areas of future research and speculation, inviting undue experimentation in learning how to make Applicants' invention. Applicants may well now be identifying molecules with the desired enzyme inhibiting properties, but the question here is what structures they possessed at the time of filing. Anything is possible but as the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences wrote in *Bindra v. Kelly*, 206 USPQ 570 "*Probable* utility does not establish practical utility. Practical utility can, in our view, be established only by actual testing therefore, or by establishing such facts as would be convincing that such utility could be "foretold with certainty." *Blicke v. Treves*, supra, 112 USPQ at 475."

4. Claims 16-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the compounds of Formula I on page 5, does not reasonably provide enablement for making all the carboxylic acid hydroxamide compounds with the desired aggrecanase activity they intend to use. The specification does not enable any skilled process chemist or pilot-plant operator to make the invention commensurate in scope with these claims. Since

Applicants do not specify the structures of the compounds they intend to use, how can the skilled process chemist be expected to make these compounds?

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Making any particular substrate would require ascertaining its chemical structure, devising a synthesis of the compound, and successfully preparing the substance in the laboratory. Since there is no direction concerning the first step, no degree of experimentation would be sufficient to perform this task. b) The direction concerning compound synthesis is found in the passage spanning line 14, page 21 through line 15, page 50. This passage concerns only synthesis of compounds of formula I. There is no direction concerning the synthesis of any other compounds meeting Applicants claim limitations. c) There are working examples of synthesis of compound of formula (I) in the passage spanning line 1, page 65 to line 32, page 82. There are no working examples of synthesis of compounds not fitting formula I.

d) The nature of the invention requires both chemical synthesis, which involves chemical reactions, and therapeutic activity. e) The state of the art is that directions to the enzymologist for how to seek such compounds hardly constitute directions to the chemist of how to make them.. f) The artisan using Applicants invention to prepare the claimed compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. He would not have the ability to make compounds whose structure he does not know. g) Chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. h) The breadth of the claims includes the six diseases mentioned in claim 16 as well as the presently unknown list of compounds embraced by claim 16.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

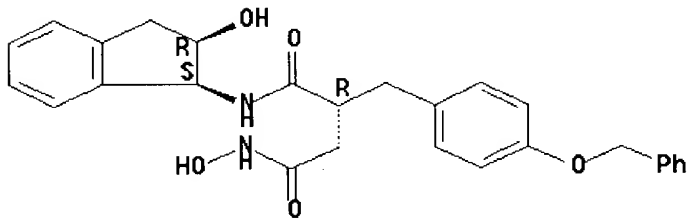
Applicants point to their working examples and assert that they are enabled for making all compounds whose use is presently claimed. This is not persuasive, making compounds whose structures are known has no relevance to the task of making compounds whose structure are unknown. Secondly, Applicants are instructed to look at page 1438 of Judge Larimer's opinion from the District Court from the Western District of New York, *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424. The screening of 600 existing compounds over an eight-month period was given as an example of undue experimentation. Can one imagine what Judge Larimer's would have thought of the amount of experimentation required to make those 600 compounds? Yet Applicants are claiming potentially billions of compounds by claiming a biological activity. Do Applicants intend to apply trial and error methods to the synthesis of all the compounds whose use they claim?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious by Yau ('664). There is one N-hydroxyl carboxyl amide compound that also contains a benzyl ether of a phenol taught in this reference. That compound is shown below. It fits the partial formula of claim 16 with $R^5 = R^6$ = hydrogen. It has registry number 220681-99-2 and may be found in column 66, line 16 of the reference. It is compound 10. The ability of this compound to inhibit the enzyme aggrecanase and to treat arthritis is taught in lines 25-33, column 4. The reference is silent as to the IC_{50} of aggrecanase enzyme



inhibition exhibited by this compound. However, "recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not

possess the characteristic relied on. [58 CCPA at 1031, 439 F.2d at 212-13, 169 USPQ at 229.] This burden was involved in *In re Ludtke*, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics." *In re Swinehart*, 58 CCPA 1027, 439 F.2d 210, 169 USPQ 226 (1971), *In re Best, Bolton, and Shaw,* 195 USPQ 430 (CCPA 1977).

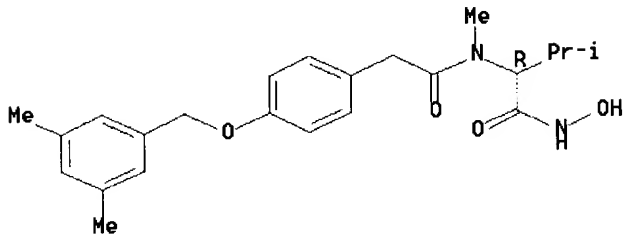
Applicants state that the compound picture above has an extra methylene group connecting the benzyloxy phenyl radical and the required hydroxyamide group. This methylene group is not found in the present claim 16, they argue. Secondly, Applicants argue that their potency limitation of $IC_{50} < 20nM$ somehow makes the claim unobvious over the art. Thirdly, they argue that the Examiner selected only one of the many compounds taught in the reference and that this is an *In re Baird* situation. Firstly, in fact there are two methylene groups CH_2 and one methine group CH in the chain connected the two required functional groups. The absence of a linking methylene group is not a limitation in the present claims. In fact, at present, anything can connect these two required groups as long as a molecular weight of less than 2000 is maintained. The molecular weight of the compound shown above is less than 2000.

Secondly, the rejection is an inherency rejection. The art is silent as to the IC_{50} possessed by the taught compound. However, the fact that it does inhibit aggrecanase and is used to treat the same medical conditions that Applicant teaches in his specification can be treated by such potent inhibitors, means that the compound must possess such an ability.

Thirdly, the Examiner did not use a generic formula to make the rejection, as was done in *re Baird* 29 USPQ2d 1550. The Examiner used a specific compound found in the reference possessing all the limitations of Applicants claim. The examiner did not have to make a single choice of any variable from any Markush list to arrive at the structure. A real, enablement compound was used to make the rejection. No generic formula was recited in the rejection. Frankly, the point of this argument requires clarification.

6. Claims 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious by Duan ('665). There are eight N-hydroxyl carboxyl amide compound that also contains a benzyl ether of a phenol taught in this reference. One such compound is shown below. It fits the partial formula of claim 16 with $R^5 = R^6 =$ *m*-methyl. It has registry number 301162-25-4 and may be found in column 47, line 20. It is compound 23. The other anticipatory compounds are found throughout Table 1 of the reference. The

ability of these compounds to inhibit aggrecanase in taught in lines 40-43, column 101. The ability to treat inflammatory diseases is taught in lines 3-18, column 102. The



reference is silent as to the IC_{50} of aggrecanase enzyme inhibition exhibited by this compound. However, "recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. [58 CCPA at 1031, 439 F.2d at 212-13, 169 USPQ at 229.] This burden was involved *In re Ludtke*, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics." *In re Swinehart*,

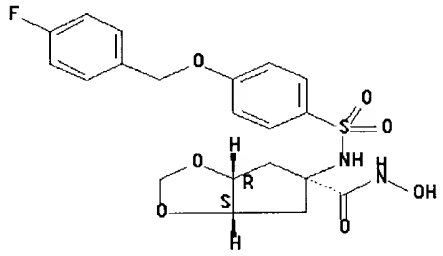
58 CCPA 1027, 439 F.2d 210, 169 USPQ 226 (1971), *In re Best, Bolton, and Shaw,* 195 USPQ 430 (CCPA 1977).

Applicants argue that the 3,5-dimethylbenzyl radical in the compound pictured above "is far removed from the substituent of Claims 16-20, benzyloxyphenyl. Indeed, that radical is much further removed from the claim substituent than is the substituent taught in Yao et al." Again Applicants are arguing limitations that are not present in the claims. The radical pictured in claim 16 is not limited to benzyloxyphenyl. The two methyl substituents of the prior art are expressly permitted by the present claims.

7. Claims 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by McClure ('870). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

There are three N-hydroxyl carboxyl amide compounds that also contain a benzyl ether of a phenol taught in this reference. One such compound is shown

below. It fits the partial formula of claim 16 with R^5 = *p*-fluoro. It has registry number 298195-25-2 and may be found in the passage spanning line 46, column 35 to line 8, column 36. It is Example 7. The other anticipatory compounds are Examples 6 and Example 8. Inhibition of aggracanase is taught the passage spanning line 66, column 1 to line 2, column 2. Treatment of arthritis with these compounds is found in claim 30 of the reference. The reference is silent as to the



IC_{50} of aggrecanase enzyme inhibition exhibited by this compound. However, "recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. [58 CCPA at 1031, 439 F.2d at 212-13, 169 USPQ at 229.] This burden was involved

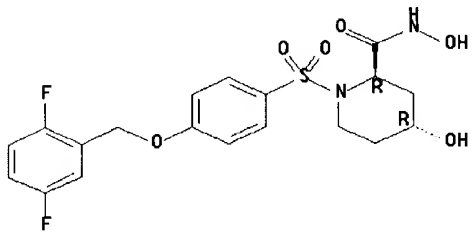
In re Ludtke, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics." *In re Swinehart*, 58 CCPA 1027, 439 F.2d 210, 169 USPQ 226 (1971), *In re Best, Bolton, and Shaw,* 195 USPQ 430 (CCPA 1977).

Applicants correctly assert that the standard for making an inherency rejection, which this is, requires inherency must be certain, *In re Rijckaert* 28 USPQ2d 1955, *In re Oelrich* 212 USPQ 323, *In re Robertson*, 49 USPQ2d 1949. In lines 21-28, page 8 of the specification, Applicants teach that one characteristic of a compound with an IC_{50} <20 in the aggrecanase enzyme assay is its ability to treat the inflammatory disease arthritis. The ability of the compound pictured above to treat inflammatory diseases was discussed above. External evidence is not required to make an inherency rejection and the Examiner may rely upon scientific reasoning, *Ex parte Levy*, 17 USPQ2d 1461. Scientific reasoning leads one to the conclusion that a compound taught to inhibit aggrecanase enzyme and also taught to treat inflammatory diseases must have the potency required.

8. Claims 16-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by McClure ('397). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

There are sixty-six N-hydroxyl carboxyl amide compounds that also contain a benzyl ether of a phenol taught in this reference. One such compound is shown below. It fits the partial formula of claim 16 with R^5 = *o*-fluoro and R^6 = *m*-fluoro. It has registry number 258860-57-0 and may be found in columns 71 and 72 of the reference. It is Example 41. The other anticipatory compounds may be found throughout Tables I-IV. Inhibition of aggracanase is taught the passage spanning line 66, column 1 to line 2, column 2. Treatment of arthritis with these compounds is found in claim 68 of the reference. The reference is silent as to the IC_{50} of



aggrecanase enzyme inhibition exhibited by this compound. However, "recitation of a newly discovered function or property, inherently possessed by things in the

prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. [58 CCPA at 1031, 439 F.2d at 212-13, 169 USPQ at 229.] This burden was involved *In re Ludtke*, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics." *In re Swinehart*, 58 CCPA 1027, 439 F.2d 210, 169 USPQ 226 (1971), *In re Best, Bolton, and Shaw,* 195 USPQ 430 (CCPA 1977).

Applicants make the same argument concerning the certainty required for an inherency rejection that was employed in point #7 above. In lines 21-28, page 8 of the specification, Applicants teach that one characteristic of a compound with an IC_{50} <20 in the aggrecanase enzyme assay is its ability to treat the inflammatory disease arthritis. The ability of the compound pictured above to treat arthritis is found in claim 68 of the reference. This is the same use claimed by Applicants. Scientific reasoning leads one to the conclusion that a compound taught to inhibit aggrecanase enzyme and also taught to treat arthritis must have the potency

required. Additionally, the discovery of a new mechanism of action does not make an old method of use patentable. *Ex parte Novitski* 26 USPQ2d 1389.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-20 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30 of U.S.

Patent No. 6,214,870. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons discussed above.

Applicants point to the generic claim 1 of U.S. Patent No. 6,214,870 and assert that the Examiner had no reason to choose the species discussed above in point #7 from that generic claim. In fact, the Examiner did not use the generic formula or claim 1 to make the rejection but rather the three species taught in U.S. Patent No. 6,214,870, which meet Applicants claim limitations. There is no In re Baird situation.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be

commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-20 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 68 of U.S. Patent No. 6,329,397. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons discussed above.

Applicants point to the generic claim 1 of U.S. Patent No. 6,329,397 and assert that the Examiner had no reason to choose the species discussed above in point #8 from that generic claim. They state "Applicants do not attempt to venture a guess as to which of the meanings of Ar, which is defined by language spanning almost two columns, is applied in the rejection of claims 16- 20." In fact the Examiner did not use the generic formula or claim 1 to make the rejection but rather the sixty-six species taught in U.S. Patent No. 6,329,397, which meet Applicants claim limitations. There is no *In re Baird* situation. Applicants need not guess which definition of Ar from U.S. Patent No. 6,329,397 the Examiner is using. It is the Ar recited in each of these sixty-six species. The Ar group under is, of course not a part of the present claim limitations.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Mukund Shah
Supervisory Patent Examiner
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TCMcK

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